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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,577	05/26/2005	Andreas Bergmann	2582.009	2150

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HESLIN ROTHENBERG FARLEY & MESITI PC
5 COLUMBIA CIRCLE
ALBANY, NY 12203

EXAMINER	
WEN, SHARON X	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
10/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,577	BERGMANN ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 04/27/2010, has been entered.

Claims 1-12 have been canceled.

Claims 13-17 are pending and currently under examination as they read on a method of for the detecting thyroid stimulating hormone (TSH) receptor autoantibodies in a biological sample.

2. Applicant's election of serum as the specific biological sample in the reply filed on 08/12/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Upon further consideration, the examination as been extended to plasma.

3. This Action will be in response to Applicant's Arguments/Remarks, filed 04/27/2010.

The rejections of record can be found in the previous Office Actions.

New grounds of rejection set forth herein necessitated this Office Action being Non-Final.

4. Upon further consideration, the previous rejection under 35 U.S.C. 102(b) as being anticipated by Parmentier et al. (U.S. Patent 6,228,597 B1, reference of record, see entire document) as evidenced by Weir et al. (*Handbook of Experimental Immunology in Four Volumes*, Volume 1: Immunochemistry, Forth Edition, 1986, Blackwell Scientific Publications, Palo Alto, CA, USA, pages 34.7-34.8, reference of record) has been withdrawn in view of Applicant's remarks/amendment, filed 04/27/2010.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. In view of Applicant's argument and amendment, filed 04/27/2010, the previous rejected under 35 U.S.C. 103(a) as being unpatentable over Parmentier et al. (U.S. Patent 6,228,597 B1) in view of Morris et al. (Autoimmunity 1994, 17:287-299). has been withdrawn.

7. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergmann et al. (WO98/26294, cited on IDS) as evidenced by U.S. Patent 6,537,760 (cited on IDS, hereafter referred to as '760), which is the English translation of the 371 application of the PCT application of WO98/26294, in view of Morris et al. (Autoimmunity 1994, 17:287-299, record of reference).

Bergmann et al. taught a method for the detection of TSH receptor autoantibodies in a serum comprising contacting said biological sample with TSH receptor that is immobilized on a solid support in the presence of labeled primary competitor in to competitively bind to the TSH receptor and detecting TSH receptor autoantibodies in the serum by measuring the amount of label bound to the TSH receptor (see'760 abstract and column 6). Moreover, Bergmann et al. also contemplated using lableled autoantibodies as the primary competitor (see '760 column 9, line 7). Given that autoantibodies to TSH receptor is the pathogenesis of Graves' disease, the antoantibodies taught by Bergmann would necessarily be from sera of human Graves' disease patients.

Although Bergman et al. did not explicitly teach the labeled anti-TSH receptor autoantibodies were obtained by affinity purification against THS receptor, it would have

been obvious to one of ordinary skill in the art, at the time of the invention was made, to perform affinity purification using TSH receptor as the antigen of choice as well as using the affinity-purified anti-TSH receptor autoantibodies as a labeled antibody in the detection assay because affinity purification of anti-TSH receptor autoantibodies from Graves' patient's sera in view of Morris et al. (see entire document). In particular, Morris et al. taught using human TSH receptor extracellular domain peptides as the antigen in the affinity chromatography for the purification of anti-TSH receptor autoantibodies (see e.g., **Introduction** on page 288 and **Affinity Purification of Anti-TSHr Autoantibodies** on page 289). One of ordinary skill in the art would have been motivated to use the extracellular domain peptides of the TSH receptor taught by Morris to affinity purify the anti-TSH-receptor autoantibodies because Bergmann et al. taught that using the labeled autoantibodies would considerably increase the range of use of the assay (see '760 column 9, lines 10-12). Furthermore, one of ordinary skill in the art would have reasonable expectation of success to use the TSH receptor for affinity purification because it is within his/her technical grasp at the time of the invention was made. Moreover, it would also be routine to check the specific activity, as a result-effective variable, of the purified antibodies in a bioassay such as that disclosed by Morris et al. (see Thyroid Stimulating Antibody Bioassay on page 289).

Therefore, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The previous rejection on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,228,597 has been withdrawn in view of Applicant's remarks/amendment, filed 04/27/2010.

9. Claims 13-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,537,760 in view of Morris et al. (Autoimmunity 1994, 17:287-299). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

Claim 1 of '760 taught a method of determining the amount of TSHr autoantibodies in a serum comprising contacting said biological sample with TSH receptor that is immobilized on a solid support in the presence of labeled primary competitor in to competitively bind to the TSH receptor and detecting TSH receptor autoantibodies in the serum by measuring the amount of label bound to the TSH receptor. Although the patented claim did not teach using labeled autoantibodies as the primary competitor, in view of the specification which stated using labeled autoantibodies in the assay (see column 9, line 7), it would have been obvious to one of ordinary skill in the art to use the labeled autoantibodies in the assay. Given that autoantibodies to TSH receptor is the pathogenesis of Graves' disease, the antoantibodies taught by Bergmann would necessarily be from sera of human Graves'

disease patients. It also would have been obvious to affinity purify the autoantibodies in view of Morris et al for reasons discussed above.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Primary Examiner, Art Unit 1644
October 18, 2010